

### REMARKS

This amendment accompanies a request for continued examination (“RCE”).

In response to the final office action dated April 22, 2009 and the advisory action dated July 28, 2009, Applicants have amended claims 1 and 2. Support for the amendment to claim 1 can be found, e.g., in paragraphs [0012] and [0088] of the specification. Claims 1-7 are presented for examination.

Initially, Applicants would like to thank the Examiner for the telephone interview with their counsel held on August 25, 2009. A letter dated August 21, 2009 was sent to the Examiner to facilitate discussion in the interview. A copy of this letter is attached hereto as “Exhibit A” to serve as a partial summary of the interview. Other points discussed during the interview are summarized below.

#### Rejection under 35 U.S.C. §103(a)

In the final office action, claims 1, 2, and 4-7 are rejected as obvious from Fuke et al., EP 0997182 (“Fuke”) in view of Nakagawa et al., U.S. Patent No. 5,071,887 (“Nakagawa”) and Kozawa et al., U.S. Patent No. 6,605,218 (“Kozawa”). Claim 3 is rejected as obvious from Fuke in view of Nakagawa and Van’t Hoft et al., U.S. Patent No. 5,514,413 (“Van’t Hoft”).

Independent claim 1 is discussed first. Claim 1, as amended, recites a plurality of selectively permeable polysulfone-based hollow fiber membranes, each of which has an inner surface for contacting blood and an outer surface for contacting a dialyzing fluid. In addition, the content of a hydrophilic polymer (e.g., polyvinyl pyrrolidone) in the outer surface of the hollow fiber membrane is 25 to 50 mass %.

As discussed in Applicants’ reply filed on July 20, 2009, none of the cited references, i.e., Fuke, Nakagawa, Kozawa, and Van’t Hoft, discloses or renders obvious a membrane containing 25 to 50 mass % of a hydrophilic polymer in the outer surface, as recited by claim 1.

In the advisory action, the Examiner did not dispute the above arguments, but asserted that “the features upon which applicant relies are not recited in the rejected claims. Namely, that the outer surface [referred to by the applicant] is only a portion of the total outer surface of the hollow fiber (Applicant suggests that the outer surface does not include the inner lumen which is also exposed to the outer atmosphere).” See page 2. The Examiner further asserted that

"[r]ecitation of 'outer' surface refers to the surface being exposed to the outer atmosphere and not another layer of the hollow fiber; Fuke's surface, that contains the predominant amount of PVP, is exposed to blood and therefore is an outer surface. ... Applicant's choice of words in the claim makes it much more broader than the argument portrays." Applicants do not necessarily agree with the Examiner's interpretation of the phrase "outer surface" recited in claim 1 or the Examiner's characterization of the membrane described in Fuke. However, in the sole interest of expediting prosecution, Applicants have limited claim 1 to a hollow fiber membrane having an inner surface for contacting blood and an outer surface for contacting a dialyzing fluid. It would have been apparent to one skilled in the art that, in a membrane of amended claim 1, the outer surface for contacting a dialyzing fluid, not the inner surface for contacting blood, contains 25 to 50 mass % of a hydrophilic polymer. By contrast, Fuke clearly teaches that the internal surface of its hollow fiber membrane is used to contact blood and that the PVP content in the internal surface of its membrane is 30 to 45% by weight. *See, e.g.*, paragraph [0023]. Given that the PVP content in the entire membrane described in Fuke is at most 10% by weight (*see, e.g.*, the abstract and paragraph [0017]), one skilled in the art would readily recognize that the PVP content in the outer surface of Fuke's membrane is significantly lower than 10% by weight, and therefore significantly different from 25 to 50 mass % as recited by claim 1. In other words, Fuke does not disclose or even suggest a membrane containing 25 to 50 mass % of a hydrophilic polymer in the outer surface for contacting a dialyzing fluid, as recited by claim 1.

As discussed in Applicants' July 20, 2009 reply, the other three cited references, i.e., Nakagawa, Kozawa, and Van't Hoff, do not cure the deficiencies in Fuke. Thus, claim 1, as well as claims 2-7 depend from claim 1, would not have been obvious from Fuke in view of Nakagawa, Kozawa, and Van't Hoff.

During the above-mentioned interview, the Examiner acknowledged that Fuke does not disclose or renders obvious a membrane containing 25 to 50 mass % of a hydrophilic polymer in the outer surface, and indicated that she would reconsider the patentability of amended claim 1 in view of the other prior art known to her.

Accordingly, Applicants request reconsideration and withdrawn of these obviousness rejections.

Applicant : Kimihiro Mabuchi et al.  
Serial No. : 10/582,052  
Filed : November 22, 2006  
Page : 7 of 7

Attorney's Docket No.: 19461-0004US1 / 547267

Double patenting rejections

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over (1) claims 1-9 of co-pending Application No. 10/559,544 and (2) claims 1-6, 16, and 17 of co-pending Application No. 10/599,167.

Applicants request that these two rejections be held in abeyance until claims 1-7 are otherwise in condition for allowance.

CONCLUSION

Applicants submit that the obviousness rejections asserted by the final Office action have been overcome.

Any circumstance in which Applicants have: (a) addressed certain comments of the Examiner does not mean that Applicants concede other comments of the Examiner; (b) made arguments for the patentability of some claims does not mean that there are not other good reasons for the patentability of those claims and other claims; or (c) amended or canceled a claim does not mean that Applicants concede any of the Examiner's positions with respect to that claim or other claims.

The \$490.00 fee for the Petition for Two-Month Extension of Time and the \$810.00 fee for the RCE are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges to deposit account 06-1050, referencing Attorney's Docket No. 19461-0004US1.

Respectfully submitted,

Date: September 9, 2009

/Tony Zhang/

Tony Zhang, Ph.D.  
Reg. No. L0256

Fish & Richardson P.C.  
601 Lexington Avenue – 52<sup>nd</sup> Floor  
New York, NY 10022  
Telephone: (212) 765-5070  
Facsimile: (877) 769-7945  
30500603.doc